

CLAIMS

1. A method of accelerating a dose of particles in a needleless injection device having a driver chamber and a duct section downstream of said driver chamber, the  
5 method comprising:  
opening closure means located between said driver chamber and said duct section;  
producing a primary shock wave travelling in a downstream direction in said duct section;  
10 establishing a substantially quasi-steady flow of fluid in said duct section upstream of said primary shock wave; and  
entraining and accelerating substantially all the dose of particles in said substantially quasi-steady flow for the duration of time that said particles are in said duct section.  
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2. A method of accelerating a dose of particles in a needleless injection device according to claim 1, wherein the duct section is of substantially constant cross-sectional area and the method further comprises initiating a starting process when said primary shock wave reaches the downstream end of said substantially constant  
20 cross-sectional area duct section.
3. A method of accelerating particles according to claim 2, wherein said step of entraining and accelerating said particles is carried out in said duct section of substantially constant cross-sectional area.  
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4. A method of accelerating a dose of particles in a needleless injection device according to claim 1, 2 or 3, further comprising producing a secondary shock wave travelling in a downstream direction behind said primary shock wave.
- 30 5. A method of accelerating particles according to claim 4, wherein said quasi-steady flow is established upstream of said secondary shock wave.

6. A method of accelerating particles according to any one of the preceding claims, wherein said particles are entrained and accelerated from an initial position upstream of said closure means.

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7. A method of accelerating particles according to any one of the preceding claims, wherein said particles are not accelerated through a constriction downstream of said closure means.

10 8. A method of accelerating particles according to any one of the preceding claims, wherein said closure means is a first closure means and the method further comprises opening a further closure means before opening said first closure means.

9. A method of accelerating particles according to any one of the preceding  
15 claims, further comprising directing said quasi-steady flow of fluid through a divergent nozzle positioned downstream of said duct section.

10. A method of accelerating particles according to claim 9, wherein said quasi-steady flow directed through said divergent nozzle portion is substantially correctly  
20 expanded.

11. A method of accelerating particles according to claim 9 or 10, wherein said quasi-steady flow directed through said nozzle portion exits the downstream end of said device with a velocity distribution that is substantially uniform over a cross-  
25 section thereof.

12. A method of accelerating particles according to any one of claims 9, 10 or 11, wherein said divergent nozzle portion has an internal contour such that substantially no oblique shocks are formed in the part of said quasi-steady flow in which said  
30 particles are entrained.

13. A method of accelerating particles according to any one of claims 9 to 12, further comprising spacing said needleless injection device from a target plane; creating a substantially normal shock wave at the exit of said divergent portion;
- 5        decelerating the particles in said substantially normal shock wave so as to have a generally radially uniform velocity as they impact the target plane.
14. A method of accelerating particles according to any one of claims 9 to 13, further comprising the step of initiating a ( $u-a$ ) wave at the downstream end of said
- 10   duct section.
15. A method of accelerating particles according to claim 14, wherein said quasi-steady flow is established upstream of said ( $u-a$ ) wave.
- 15   16. A method of accelerating particles according to any one of the preceding claims, further comprising creating an expansion wave which travels in an upstream direction from the location of said closure means.
17. A method of accelerating particles according to claim 16, further comprising
- 20   reflecting said expansion wave so that it travels in a downstream direction.
18. A method of accelerating particles according to claim 17 wherein said quasi-steady flow is terminated when said reflected expansion wave passes out of the downstream end of the device.
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19. A method of accelerating particles according to any one of the preceding claims, further comprising the step of selecting the driver gas species, or combination of species, so as to control the velocity of the particles as they exit the device.
- 30   20. A needleless injection device comprising:
- a driver chamber arranged, in use, to contain a charge of pressurised gas;
- a duct section connected to said driver chamber to receive gas therefrom;

closure means for preventing the flow of gas from said driver chamber to said duct section until said closure means is opened; and

a dose of particles positioned within the device in the region of said closure means;

- 5           said device being so constructed and arranged that upon opening of said closure means, a primary shock wave is produced to travel along said duct section in a downstream direction and a substantially quasi-steady gas flow is established in said duct section upstream of said primary shock wave, said dose of particles being substantially wholly entrained in said substantially quasi-steady flow to be  
10   accelerated thereby and expelled from the device.

21.   A needleless injection device according to claim 20, wherein the device is arranged so that said primary shock wave initiates a transient starting process upon reaching the downstream end of the duct section.

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22.   A needleless injection device according to claim 20 or 21, wherein said closure means is positioned at the downstream extent of said driver chamber.

23.   A needleless injection device according to any one of claims 20 to 22,  
20   wherein said driver chamber is pre-charged with pressurised gas.

24.   A needleless injection device according to any one of claims 20 to 22, further comprising a source of gaseous fluid, said driver chamber being fluidly connected to said source and arranged to be provided with said charge of pressurised gas by said  
25   source upon opening of the fluid connection therebetween.

25.   A needleless injection device according to claim 24, wherein said fluid connection consists of a bleed hole of a size small enough substantially to de-couple said driver chamber from said source of gaseous fluid upon opening of said closure  
30   means.

26. A needleless injection device according to any one of claims 20 to 25, wherein said duct section comprises a tube of substantially constant cross-sectional area.
- 5 27. A needleless injection device according to any one of claims 20 to 26, in which said particles are positioned upstream of said closure means.
- 28 A needleless injection device according to any one of claims 20 to 27, wherein said duct section includes substantially no convergent portion therein  
10 downstream of said closure means.
29. A needleless injection device according to any one claims 20 to 28, further comprising a divergent nozzle portion positioned downstream of said duct section.
- 15 30. A needleless injection device according to claim 29, wherein said divergent nozzle portion has an inlet cross-sectional area and an exit cross-sectional area, said areas being chosen in accordance with the total driver chamber pressure at which said device is arranged to operate so that, in use, the gas flow in said divergent portion is substantially correctly expanded when said particles pass through said divergent  
20 portion.
31. A needleless injection device according to claim 29 or 30, wherein said divergent nozzle portion has an internal contour such that substantially no oblique shock waves are formed in said substantially quasi-steady flow.
- 25 32. A needleless injection device according to any one of claims 29 to 31, wherein said divergent nozzle portion is contoured such as to cause any expansion downstream of the duct section to provide a generally radially uniform particle distribution at the exit of the divergent portion and a generally radially uniform  
30 particle velocity distribution, with a substantially parallel velocity of particles and gas exiting the device.

33. A needleless injection device according to any one of claims 29 to 32, further comprising a spacer positioned at the downstream end of the device, the spacer being constructed so as to space a target plane downstream of the divergent nozzle portion exit with a clearance sufficient to allow:

5 a substantially normal shock wave to be positioned downstream of the exit of said divergent nozzle portion; so that

said normal shock interacts, in use, with the gas and particle jet from said device to provide a substantially controlled and uniform gas stagnation region which decelerates the particles to a generally uniform velocity as they impact the target  
10 plane.

34. A needleless injection device according to any one of claims 20 to 37, wherein said driver chamber comprises a substantially constant area tube.

15 35. A needleless injection device according to any one claims 20 to 34, wherein said driver chamber comprises a convergence at its downstream end, positioned upstream of said closure means.

20 36. A needleless injection device according to any one claims of claims 20 to 35, wherein said closure means comprises a rupturable membrane arranged to open by rupturing.

37. A needleless injection device according to claim 36, wherein said rupturable membrane is arranged to rupture in a controlled way due to an indentation on, or  
25 scoring of, the membrane surface.

38. A needleless injection device according to any one claims 20 to 37, wherein said device contains a further closure means.

30 39. A needleless injection device according to claim 38, wherein said further closure means is positioned in said driver chamber upstream of said particles.

40. A needleless injection device according to claim 38 or 39, wherein said further closure means comprises a rupturable membrane arranged to open by rupturing.

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41. A needleless injection device according to claim 40, wherein said rupturable membrane is arranged to rupture in a controlled way due to an indentation on, or scoring of, its surfaces.

10 42. A particle retention assembly of or for use in a needleless injection device; said assembly comprising:

first closure means arranged to open when the pressure across it is  $P_1$ ; and

second closure means which, in use, is located upstream of said first closure means and which is arranged to open when the pressure across it is  $P_2$ ;

15 wherein  $P_1$  and  $P_2$  are different.

43. An assembly according to claim 42, wherein  $P_1$  is greater than  $P_2$ .

44. An assembly according to claim 42, wherein  $P_2$  is greater than  $P_1$ .

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45. A particle retention assembly of or for use in a needleless injection device; said assembly comprising:

first closure means arranged to open when the pressure across it is  $P_1$ ;

second closure means which, in use, is located upstream of said first closure

25 means and which is arranged to open when the pressure across it is  $P_2$ ;

a transfer duct which fluidly connects a location upstream of said second closure means to a location between said first and second closure means.

46. A particle retention assembly according to claim 45, wherein said transfer  
30 duct is arranged to direct a jet of gas from upstream of said second closure means so as to impinge on any particles located between said first closure means and said

second closure means so as to create a gas/particle cloud between said first and second closure means.

47. A particle retention assembly according to claim 45 or 46, further comprising  
5 transfer duct closure means in said transfer duct.

48. A particle retention assembly according to claim 47, wherein said transfer duct closure means is arranged so as to open when the pressure across it is  $P_T$ , wherein  $P_T$  is less than  $P_2$ .

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49. A particle retention assembly according to any one of claims 45 to 48, wherein said transfer duct is positioned in said second closure means.

50. A particle retention assembly according to any one of claims 42 to 49, further  
15 comprising a dose of particles located between said first and second closure means.

51. A particle retention assembly according to any one of claims 42 to 50, wherein some or all of said various closure means are each constituted by a rupturable membrane which is scored or indented to provide controlled rupturing.

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52. A particle retention assembly of or for use in a needleless injection device; said assembly comprising:

first closure means arranged to open when the pressure across it is  $P_1$ ;

second closure means which, in use, is located upstream of said first closure  
25 means and which is arranged to open when the pressure across it is  $P_2$ ;

wherein one of said first and second closure means are constituted by rupturable membranes which are scored or indented so as to provide controlled rupturing.

30 53. A particle retention assembly according to claim 52, wherein said scored or indented rupturable membrane is scored or indented along one or more radial lines.



54. An assembly according to any one of claims 42 to 53, wherein the assembly is of, or for use in, a needleless injection device having the construction claimed in any of claims 20 to 41.
- 5 55. A needleless injection device comprising the assembly of any one of claims 42 to 54.
56. A method of needleless injection involving the injection of particles into bodily tissue, the method comprising accelerating the particles in a needleless  
10 injection device using the method of particle acceleration claimed in any one of claims 1 to 19.
57. A method of entraining a dose of particles in a gas flow in a needleless injection device, the method comprising:
- 15 opening an upstream closure means when the pressure difference thereacross is  $P_2$  to produce a cloud of gas;  
entraining said particles in said cloud of gas; and  
opening a downstream closure means when the downstream closure means is exposed to said cloud of gas and entrained particles and when the pressure difference  
20 across said downstream closure means is  $P_1$ ;  
wherein  $P_1$  is different to  $P_2$ .
58. A method of entraining a dose of particles in a gas flow in a needleless injection device, the method comprising:
- 25 providing a duct having upstream and downstream closure means;  
providing a transfer duct which is arranged to permit gas from upstream of said upstream closure means to be introduced into the space between said upstream closure means and said downstream closure means.
- 30 59. A method of entraining a dose of particles according to claim 58, further comprising causing a jet of gas to impinge on any particles located between said upstream closure means and said downstream closure means so as to create a

gas/particle cloud between said upstream closure means and said downstream closure means.

60. A method of entraining a dose of particles according to claim 58 or 59,  
5 further comprising providing a transfer duct closure means in said transfer duct.

61. A method of entraining a dose of particles according to claim 60, further  
comprising opening said transfer duct closure means when the pressure across it is  
 $P_T$ , this pressure being less than the pressure at which said upstream closure means  
10 opens at.

62. A method of entraining a dose of particles according to any one of claims 58  
to 61, further including the steps of allowing gas to pass through a small aperture in  
said upstream closure means; and  
15 causing said upstream closure means to rupture after some gas has passed  
therethrough into said space between said upstream and downstream closure means.

63. A method of needleless injection involving the injection of particles into  
bodily tissue, the method comprising entraining the particles in a gas flow in a  
20 needleless injection device using a method of particle entrainment according to any  
one of claims 58 to 62.